K091585
pg 1 of 2

510(k) SUMMARY

DEC 29 2009

V.A.C.® Therapy Systems

Date prepared	December 23, 2009
510(k) owner	
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)
Address	6203 Farinon Drive; San Antonio, Texas 78249
Fax number	210 255-6727
Name of contact person	Margaret Marsh
Name of the device	
Trade or proprietary name	V.A.C.® Therapy Systems
Common or usual name	Negative Pressure Wound Therapy Systems
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
Legally marketed device(s) to which equivalence is claimed	V.A.C.® Therapy System Family of Products
Device description	The software-controlled therapy unit applies negative pressure to the wound bed. The open cells of the V.A.C.® Foam Dressing to which the therapy unit is connected enable distribution of the negative pressure across the surface of the wound, while the tubing transfers accumulated fluids to the canister. The software monitors and maintains target pressure and alarms as needed to help assure target pressure is maintained and constant therapy is delivered.

Intended use of the device	The ActiV.A.C.®, InfoV.A.C.®, V.A.C. ATS®, and V.A.C. Freedom® Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. They are intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. They are indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. The V.A.C. GranuFoam Silver® Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types. The V.A.C. Instill® Therapy System is indicated for patients who would benefit from V.A.C.® Therapy coupled with controlled delivery of topical wound treatment solutions and suspensions over the wound bed. It is intended for patients with chronic acute, traumatic, subacute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency), flaps and grafts.
Differences in intended use from the predicate(s)	The only difference between the current and the predicate products is in the addition of venous insufficiency ulcers to the Indications for Use statement.
Summary of the technological characteristics of the device compared to the predicate device	The technological characteristics of the V.A.C.® Therapy System Family of Products is unchanged.
Summary of nonclinical tests	None required for the change in indication
Summary of clinical tests	Medical literature documents acceptable clinical experience using the V.A.C.® Therapy System to treat venous insufficiency ulcers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

KCI USA
% Ms. Margaret Marsh
Regulatory Affairs Technical Director
6203 Farinon Drive
San Antonio, Texas 78249

DEC 2 9 2009

Re: K091585
Trade/Device Name: V.A.C.® Therapy System; V.A.C. Instillamet (V.A.C.® Instill)
Regulation Number: 21 CFR 878-4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 12, 2009
Received: October 13, 2009

Dear Ms. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091585
pg 1 of 2

INDICATIONS FOR USE

510(k) Number (if known): K091585

Device Name: V.A.C.® Therapy System

Indications for Use:

The ActiV.A.C.®, InfoV.A.C.®, V.A.C. ATS®, and V.A.C. Freedom® Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. They are intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. They are indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.
The V.A.C. GranuFoam Silver® Dressing is an effective barrier to bacterial penetration and may help reduce infection in the above wound types.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091585

(Posted November 13, 2003)

K091585
pg 2 of 2

INDICATIONS FOR USE

510(k) Number (if known): K091585

Device Name: V.A.C. Instillamat (V.A.C.® Instill)

Indications for Use:

The V.A.C.® Instill device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C.® Instill is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

(Posted November 13, 2003)

510(k) Number K091585